Consent Document Checklist

☐   Title of study

☐   Statement that study involves research

☐   Study sponsor's name

☐   An explanation of purpose of research

☐   How subject was selected for involvement in study

☐   Description of procedures to be followed

☐   Clearly stated what participation will involve in terms of:

    ☐   Time (both amount and frequency of participation)

    ☐   Participant effort needed

    ☐   Possible benefits

    ☐   Possible risks

    ☐   Possible discomforts

    ☐   Additional costs, if any

    ☐   Use of placebos

☐   Experimental procedures described

☐   Appropriate available alternative procedures or treatments that may help participant

☐   Statements describing how & to what extent participant's privacy & confidential information will be maintained

☐   Possible more than minimal risks disclosed

☐   Withholding usual treatment of service disclosed, if part of research protocol

☐   Possibility of unforeseen risks, if any

☐   Available medical treatment in case of injury

☐   Any incentives for subject participation and what must be done to obtain incentives disclosed

☐   Statement that participation is voluntary

☐   Statement that any current services or benefits received by participant or that participant is entitled to, from any agency named in form, will not be affected by participant's decision

☐   Statement that participant may withdraw from study at any time without consequences to any usual benefits received

☐   Procedures to withdraw from participation in research

☐   Anticipated circumstances under which subject's participation may be terminated by investigator without regard to subject's consent

☐   Statement that significant new findings developed during course of research, which may relate to subject's willingness to continue participation, will be provided to subject

☐   Approximate number of subjects involved in study

☐   How to obtain further information about study

☐   Contact information (at no cost to participant) if participant has questions about study

☐   DSHS IRB toll-free telephone number for questions about participants rights as a research subject

☐   Language and reading level appropriate for subject population